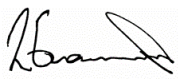
# Change Notification for the UK Blood and Tissue Services

**Notification date** 22 July 2026
**Effective date** 19 August 2026
**Implementation** To be determined by each Service

CN 24-2026

## Updates to consent guidance in the Red Book

| | Content changed | Type of change | Guidelines affected |
|---|---|---|---|
| **1** | Chapter 6:<br>Evaluation and manufacture of blood components | Updated chapter | **Red Book** |
| **2** | Chapter 8:<br>Evaluation of novel blood components, production processes and blood packs: generic protocols | Updated chapter | **Red Book** |



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**Note:** this document indicates inserted and ~~deleted~~ text. This formatting will not apply in the published text.

# 1. Chapter 6: Evaluation and manufacture of blood components

| Guidelines affected | Reason for change |
|---|---|
| Red Book | Addition of reference to guidance on informed consent in Chapter 3.4. |

The following section of the chapter will be updated. The rest of the chapter is unchanged.

## 6.2: Setting and maintaining specifications

The wide variability of the source material from which blood components are prepared makes it difficult to set stringent limits. Nevertheless, realistic minimum specifications should be set and complied with.

Concessionary release limits are also set for certain components that are subject to non-destructive quality monitoring, such that components that are excessively out of specification are only used therapeutically under specific circumstances and subject to formal clinical approval (see Table 6.1.1 to Table 6.1.13).

All blood components tested and found outside concessionary release limits should have the testing repeated to confirm the original result and the production process should be reviewed as necessary.

Some abnormal results could have implications for the health of the donor and should be reviewed by a Designated Clinical Support Officer (chapter 3.4 provides guidance on informed consent). Further samples or referral to an appropriate clinical service may be required for the donors of:

- Red Cells in Additive Solution, Leucocyte Depleted, where the Hct is >0.70.
- Platelet components collected by apheresis, where the platelet count is below any lower concessionary release limit.
- For Fresh Frozen Plasma, Leucocyte Depleted where the FVIII is <0.3IU/mL.

(the rest of chapter 6.2 is unchanged)

# 2. Chapter 8: Evaluation of novel blood components, production processes and blood packs: generic protocols

| Guidelines affected | Reason for change |
|---|---|
| Red Book | Addition of reference to guidance on informed consent in Chapter 3.4. |

The following section of the chapter will be updated. The rest of the chapter is unchanged.

## 8.1: Aims and introduction

This chapter aims to describe how a proposed novel blood component, production process or blood pack is to be evaluated to:

- Gain sufficient data to validate the component and production method.
- Gain sufficient data to support the clinical use of the component.
- Allow the Standing Advisory Committee on Blood Components (SACBC) to recommend to JPAC that the component should be included in the Red Book, either within chapter 7 as a blood component specification or within annex 3 as a provisional component specification.
- Provide sufficient information to prevent all Blood Establishments (other than those performing a full evaluation) from having to complete a full validation of the novel component before it enters routine production. They will only need to undertake installation and process validation.

The steps that a group of investigators will need to undertake to submit a novel blood component for inclusion in the Red Book, thereby allowing it to be produced on a routine basis throughout the UK, are detailed below (see 8.1.1 below).

Guidance on assessing the degree of novelty of components, to be carried out prior to embarking on the process, is also given below (see 8.1.2 below).

It is recognised that some novel components may be developed by a group of investigators in conjunction with a commercial company undertaking speculative research. As a result, the group of investigators may wish to enter the process at Step 8. In this case, SACBC will expect any requirements for data collection in the preceding steps to be complied with when the protocols and reports are submitted to SACBC for consideration. If sufficient data are not included then a request for extra data will be made (Step 9).

It is also recognised that there may be a need for Blood Establishments to produce blood components for clinical use on a temporary basis. This may be to undertake a clinical study or operational assessment of a

new component in order to inform the decision as to whether there is a need to manufacture the component on an ongoing basis. In such circumstances, the most appropriate course of action is to seek approval for a provisional component specification (see 8.1.3 below).

Guidance on how specific novel components should be tested is included in the following chapters:

- For red cell components, see chapter 8.2
- For platelet components, see chapter 8.3
- For plasma components, see chapter 8.4
- For plasma for fractionation for immunoglobulin manufacture, see chapter 8.5

This guidance is followed by information on generic protocols for the evaluation of apheresis equipment (see chapter 8.6) and blood packs (see chapter 8.7).

For guidance on phases of validation and sample size, please see 8.1.4 below.

With novel components or processes, it is important to consider informed consent of any donors and recipients. Additional guidance on informed consent can be found in chapter 3.4.

## 8.1.1: Steps for evaluation of novel components

**Step 1 - Investigators identify requirement for a novel blood component**

**Information**

The new component may be derived from a commercially available product. In this case, data to support the submission may be derived from the manufacturer.

Investigators must critically appraise data already available.

All data must be maintained on file. Data will be used to demonstrate validation has been completed in support of Blood Establishment licensing activities. Data required may include clinical outcome.

**Details**

The requirement must be derived from research and development (R&D) work or as the result of clinical discussions.

The blood component needs:

- To fulfil an unmet clinical need.
  OR
- Provide production benefit and have a Blood Service proposer.

Investigators will need preliminary data to support their application.

**Step 2 - Investigators consider whether the component should be treated as novel**

Investigators may obtain initial advice from SACBC. Likely degrees of novelty and clinical use of components are described in 8.1.2 below.

**Information**

The proposed new component may require evaluation, even if it complies with existing Red Book guidelines, if:

- A new production technique is involved (e.g. leucocyte-depleted red cells produced by apheresis).
- There are different steps in the production process (e.g. white-cell filtration immediately following collection).
- Definitive advice about the need for full-scale evaluation will be provided from SACBC following a written submission.

**Details**

If yes, the component is novel: go to Step 3.

If no, the component is not novel: undertake local validation and produce the component locally under the general principles of good manufacturing practice and the Red Book (see 8.1.4 below).

Steps 3 to 7 relate to characterisation of the blood component

**Step 3 - Investigators define the intended specification for the blood component**

**Information**

Specify all key points which will allow subsequent production of the component to be well controlled.

**Details**

Written specification to include:

- Expected characteristics (e.g. leucocyte count).
- Testing characteristics (blood grouping, microbiology etc).
- Sampling time, sampling method and sample handling conditions to confirm that the component meets specification.

Reference should also be made to the research papers from which the specification is derived.

**Step 4 - Investigators write the protocol for component evaluation (Phase 0)**

**Information**

Principles of good clinical and good manufacturing practice should apply. Comply with generic protocols (see 8.1.4 below and chapters 8.2 to 8.4). Laboratory studies should comply with local standards.

Must include in the procedure the sampling regimes, data analysis and expected ranges, which will be used to confirm that production of the component is under control.

Must include detail of the data analysis methods.

**Details**

Investigators' group writes procedures for:

- component production
- monitoring of performance
- clinical use
- outcome measurement
- adverse incidents in production/use of the blood component

or use manufacturer's documentation to produce 'in-house' protocols.

**Step 5 - Investigators should ensure their protocol complies with guidance in this chapter**

Investigators may seek advice from SACBC.

**Step 6 - Investigators obtain ethics committee approval, if required**

Must comply with local consenting and ethics policies for the use of donated material.

Consider informed consent – see chapter 3.4 for additional guidance.

(the rest of chapter 8.1 is unchanged)